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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,125	01/09/2001	Tadamitsu Kishimoto	053466/0296	6506

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
06/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/756,125	KISHIMOTO ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2007 and 09 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11-14,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *9,11-14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 5/09/07 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's remarks filed 2/23/07 have been entered.

2. Claims 9, 11-14, and 16-17 are being acted upon.

3. The specification stands objected to for the following reasons. The attempt to incorporate subject matter into this application by reference to WO 92/19759 remains improper. While Applicant has submitted a certified translation of the document and an appropriate executed declaration, it is unclear where in the WO document the actual support for the subject matter of the amendment is to be found. Note that the instant specification discloses that hPM-1 is *a* (note singular) reshaped human antibody (pages 10-11). Yet the subject matter in question refers to what would comprise an essentially unlimited number of antibodies limited only by specific V_L and V_H regions. Clearly then, the issue is twofold: 1) where specifically in the WO document is the hPM-1 antibody *comprising* the specific V_L and V_H regions (and any other C regions) to be found, and 2) how does this entire genus of antibodies describe the single hPM-1 antibody of the instant specification.

Applicant's arguments, filed 2/23/07, have been fully considered but they are not persuasive. Applicant argues that U.S. Patent No. 5,795,965 matured from WO 92/19759 and provides support for the amendments to the instant specification.

The disclosure and claims of the '965 patent are not at issue in the instant case. They will not be commented on here. It is curious, however, that Applicant has chosen to cite an unrelated patent for support of the amendments at issue here when a certified translation of the actual document at issue, WO 92/19759, is of record in this application.

A review of the WO 92/19759 translation shows at page 8 that the monoclonal antibody PM1 is produced by the mouse hybridoma PM-1 as described in Japanese Patent Application No. 2-189420. There is no indication that the terms are intended to encompass families of hybridomas and antibodies. Indeed, WO 92/19759 states, "Reference Examples 1 and 2 of the present specification describe the construction process of the hybridoma PM1", which seems to indicate a single hybridoma and antibody. Reference Example 2, page 80, then briefly describes the production of a single hybridoma that was subsequently deposited, "one hybridoma clone producing antibody which specifically bound to the IL-6R was isolated, and designated PM1. The hybridoma PM1 was deposited with the FRI under the Budapest Treaty as FERM BP-2998, on July 10, 1990".

Applicant argues that thousands of human IgG sequences are known in the art and that hundreds of humanized versions of PM-1 are described and enabled.

First note that there is no enablement rejection of record. Regarding an adequate description, the instant specification fails to describe the genus of antibodies encompassed for use by the method of the instant claims. Applicant's showing of specific support in the WO 92/19759 translation would likely facilitate the withdrawal of this objection.

Applicant argues that the disclosure at pages 10-11, "a preferred example of such a reshaped human antibody is hPM- 1" does not limit Applicant to a single antibody due to characteristics of the Japanese language and its English translation.

It must be presumed that the instant specification was translated by a competent translator, to disclose what Applicant intended it to disclose. Presumably the translation was then reviewed and approved before submission. Thus, Applicant's assertions otherwise, and offer to have the translation amended, are not found to be persuasive.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9, 11-14, and 16-17 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically: the humanized PM-1 antibody comprising the sequences of SEQ ID NOS:2-16 as set forth in Claims 9 and 13.

Applicant is advised that, as the amendment to the specification is improper, as set forth in Section 3 above, the new claims are also improper and thus, comprise the introduction of new matter into a claims.

Applicant's arguments, filed 2/23/07, have been fully considered but they are not persuasive. Applicant argues that, "The present application is unlike the situation in case such as *Lilly* or *Rochester*, as it is unchallenged that Applicants were in *actual* possession of the claimed invention".

It most certainly is challenged that Applicant was in possession of the genus of antibodies employed in the method of the instant claims.

Applicant again cites U.S. Patent No. 5,795,965 as well as U.S. Patent No. 5,888,510.

A review of the '510 patent, which is related to the instant application, fails to reveal the antibodies of the instant claims. As set forth above, the '965 patent is not part of the instant patent family and will not be discussed here.

Applicant cites *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006) and *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2006).

Neither case is particularly relevant here. *Falkner* considers that written description requirement in the context of specific DNA sequences. No specific DNA sequences are at issue here. Similarly, the issue in *Capon* was again DNA sequences. While the bulk of the court's opinion was given over to considerations of enablement, the court found that, "The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes". Such is not the issue in the instant case. No specific nucleotide sequences are under consideration here. The issue in this application is that it is unclear that Applicant ever intended the use of, or was in possession of, the family of antibodies recited in the method of the instant claims.

6. No claim is allowed.

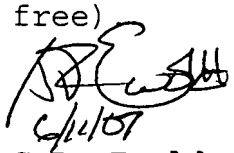
7. Regarding the IDS filed 4/28/06, the single document listed on said IDS is in Japanese. Only a "partial", uncertified translation is provided. Accordingly, the document has not been considered.

Applicant argues that the partial translation should be considered.

Upon the showing of precisely what has been translated, and the concise relevance of the partial translation to the method of the instant claims, said translation will be considered.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

9. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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